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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON *THYMUS VULGARIS* L. AND
THYMUS ZYGIS LOEFL. EX L., AETHEROLEUM**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2009 May 2009
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Thymus vulgaris</i> L.; <i>Thymus zygis</i> Loefl. ex L.; Thymi aetheroleum; thyme essential oil.
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**COMMUNITY HERBAL MONOGRAPH ON *THYMUS VULGARIS* L. AND
THYMUS ZYGIS LOEFL. EX L., AETHEROLEUM**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Thymus vulgaris</i> L. or <i>Thymus zygis</i> Loefl. ex L. or a mixture of both species, aetheroleum (thyme essential oil)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparation Essential oil</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>In liquid or semi-solid dosage forms for oral (indication 1) and cutaneous use and as a bath additive (indication 2).</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Indication 1) Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p>

¹ The material complies with the Ph. Eur. monograph (ref. 01/2008:1374).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

	<p>Indication 2) Traditional herbal medicinal product for the relief of symptoms in coughs and colds.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>
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4.2 Posology and method of administration

<p><u>Well-established use</u></p>	<p><u>Traditional use</u></p> <p>Posology</p> <p>Indication 1)</p> <p><i>Adults and elderly</i> Oral use: 4-5 drops (single dose), 3-5 times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p>Indication 2)</p> <p><i>Adults and elderly</i> Cutaneous use: in semi-solid dosage forms in concentrations up to 10%; apply up to 3 times daily. Use as bath additive: 0.007 – 0.025 g per litre.</p> <p><i>Adolescents</i> Use as bath additive: 0.007 – 0.025 g per litre</p> <p><i>Children 6-12 years</i> Use as bath additive: 0.0035 – 0.017 g per litre</p> <p>One bath every day or every second day.</p> <p>The cutaneous use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p>The use as bath additive in children under 6 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p>
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	<p>Duration of use</p> <p>Indications 1) and 2) If the symptoms persist longer than 1 week, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2) Duration of a bath: 10-20 minutes.</p> <p>Method of administration</p> <p>Indication 1) Oral use.</p> <p>Indication 2) Cutaneous use. Use as bath additive. (recommended temperature of bath: 35 – 38 °C).</p>
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4.3. Contraindications

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Hypersensitivity to the active substance.</p> <p>Use as bath additive: Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.</p>
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4.3. Special warnings and precautions for use

<u>Well-established use</u>	<p><u>Traditional use</u></p> <p>Indications 1) and 2) Like other essential oils, thyme oil should not be applied to the face particularly in the nasal area of babies and infants under the age of two years because of the risk of a laryngospasm.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 1) The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>Indication 2) Cutaneous use: The use in children and adolescents under</p>
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	<p>18 years of age is not recommended due to lack of adequate data.</p> <p>Use as bath additive: The use in children under 6 years of age is not recommended because medical advice should be sought and due to lack of adequate data. In cases of hypertension, a full bath should be used with caution.</p>
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4.4. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u>
	None reported.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Indication 1) Hypersensitivity reactions have been observed. The frequency is not known.</p> <p>Indication 2) Hypersensitivity reactions and skin irritation have been observed. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>Thyme essential oil had no mutagenic or DNA-damaging activity in either the Ames test (strains TA1535, TA1537, TA98, TA100, with and without metabolic activation) or Bacillus subtilis rec-Assay.</p> <p>Adequate tests on reproductive toxicity and carcinogenicity have not been performed.</p>

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

14 May 2009